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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,986	08/17/2000	Gregor Cevc	500.1011	9461

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,986

Applicant(s)

Cevc

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 4, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-172 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58-172 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

The request for the extension of time and amendment filed on 4-4-02 are acknowledged.

Claims included in the prosecution are 58-172.

Specification

- 1. The disclosure is objected to because of the following informalities: There is no brief description of the drawings.**

Appropriate correction is required.

Applicant's arguments that the drawings have been discussed throughout the specification are not found to be persuasive. The US practice is to have a heading, 'A brief description of the drawings' and then describe each drawing underneath.

- 2. The examiner once again reminds applicant that the lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.**

Claim Rejections - 35 USC § 112

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:**

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 58-172 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific combination of substances (first substance, second substance and third substance), specific liquid medium, does not reasonably provide enablement for claims as claimed with confusing terminology. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claims are recited in a very vague and confusing way and the specification does not provide adequate guidance as to the nature of the claimed composition.**

This rejection is maintained. According to applicant, the newly presented claims overcome the rejection. This argument is not convincing since claim 58 still recites the vague terms. For example, this claim recites three amphipathic substances, but only two of them form extended surfaces, but the other doesn't, but only gets attached to the extended surfaces. One of ordinary skill in the art will not be able to determine which amphipathic substances form extended surfaces and which do not from instant specification which provides lengthy lists of substances which overlap.

5. **The following is a quotation of the second paragraph of 35 U.S.C. 112:**

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 58-172 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Applicant cancels the originally presented claims and presents new claims with the same issues which existed before and without addressing the issues. For example, as already indicated, if a substance is soluble in a liquid (regardless of the degree of solubility) how can it form an extended surface? What is meant by an extended surface? If all three are amphipathic substances, why would only two form extended surfaces and the third one not? What is the solubility of the third amphipathic substance? The examiner had already suggested naming these substances and the third substances. 'less extended', 'more extended' are indefinite since they are relative terms.

According to claim 58, only the first and second substance form the extended surfaces; according to claim 60, even the third substance forms the extended surface. This is very confusing. Also, if all three substances have the same sign, how can they associate with each other? (See also claims 61 and 62 in this context).

Claim 61 recites three substances, yet uses the term, 'both'. The term, 'both' means two.

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Claims 67-70 depend from claim 8 which no longer exists. Similar is the case with claim 172.

What is meant by ‘average curvature’ as recited in claims 71-74? Average of what?

According to claim 86, the second and third amphopaths are surfactants and are identical. If so, it is unclear why only the second surfactant forms the extended surface and the third doesn’t?

‘Selected from the group comprising’ as recited in claims 93-97, 100-101, 111, 124, 128, 131 and 162 is not a proper expression; ‘it should have been selected from the group consisting of’.

What is the difference between ‘glycolipid’ and ‘a carbohydrate containing lipid’ as recited in claim 94?

‘Types’ in claims 97 and 101 is indefinite (also in claim 101); See Ex parte Copenhaver, 109 USPQ 118.

It is unclear whether the terms in parenthesis are indeed the limitations as recited in claim 105.

The method of preparing claim 157 is very confusing; what is meant by ‘third substance in the form of said agent molecules’? What is a controlled mechanical fragmentation? Isn’t the method for associating the third substance with the first and the second? How can this be fragmentation?

What is an ‘edge active substance’ as recited in claim 161?

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What is meant by ‘recognition molecules’, adrenocorticostatica and ‘adrenolitica’ as recited in claim 162? (similar terms are also recited in claim 126).

Applicant should have recited specific lipids in claim 93 avoiding vague terms and expressions such as ‘modification of such a lipid’, ‘corresponding synthetic lipid’, e.g., ‘other glycolipids, ‘corresponding derivatives’ to name a few (see claims 101, 105)This was already pointed out in the previous office action.

What are the those terms recited in claim 126? The examiner has already requested submission of any literature evidence that those terms are known expressions. The examiner has also suggested reciting SPECIFIC components in a proper Markush format avoiding terms such as any sleep inducing agent’ to give an example).

The examiner had already suggested a careful revision of all the claims and reciting them according to US practice so that a proper search can be made.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 58-66, and 71-171 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/03122 of record.**

WO and CA publications disclose a composition containing two or more amphiphilic substances with different solubilities for the administration of various active substances including insulin (note the abstract and entire publication, in particular, examples and claims in both).

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that WO 92 does not disclose the combination of the first, second and the third substances. This argument is not persuasive since the reference appears to teach the same combination of amphiphathic substances together with the active agents. The differences argued cannot be determined since there is no English translation.

Note: claims 67-70 and 172 are not included in the prior art rejection since they depend from canceled claims.

9. **Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk